Attorney Docket No.: CBX0007-506-US

In re the Patent Application of:	Group Art Unit: 1649
Applicant: Karin Ekberg et al.	Examiner: Stacey Nee MacFarlane
Serial No.: 10/575,701	Confirmation No.: 3695
Filed: December 11, 2006	

Certificate of Electronic Filing

I hereby certify that the attached **Petition to Withdraw Finaltiy of Rejection of Office Action** and all marked attachments are being deposited by Electronic Filing on **02/11/2010** by using the EFS – Web patent filing system and addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: /Dennis A. Bennett/

Dennis A. Bennett, Reg. No. 34,547

Title: THERAPEUTIC APPLICATIONS FOR C-PEPTIDE

Group Director Art Unit 1649
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 CFR 1.181 FOR RECONSIDERATION AND WITHDRAWAL OF THE FINALITY OF THE REJECTION OF THE LAST OFFICE ACTION.

Dear Sir:

1. A final office action was received in the above case on December 11, 2009, which introduced a new ground of rejection with respect to claims 3, 10 and 12-15 under 35 U.S.C. 102(b), and claim 11 under 35 U.S.C. 103(a) that was neither necessitated by applicants amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

2. The Office action states at paragraph 13 that the Applicants amendment necessitated the new ground(s) of rejection presented in this Office action.

3. The amendments to the pending claims in question are listed below:

1. (Canceled)

2. (Canceled)

3. (Currently Amended) A method of treating diabetes and/or microvascular diabetic complications comprising administering C-peptide or a pharmaceutical composition comprising C-peptide to a patient ~~in a~~ once daily ~~dose,~~ wherein said once daily ~~dose~~ **administration** does not include a continuous administration or the presence of release rate-controlling agents.

4. (Canceled)

5. (Canceled)

6. (Canceled)

7. (Canceled)

8. (Canceled)

9. (Canceled)

10. (Currently Amended) The method according to claim 3, wherein ~~the~~ **said** C-peptide is human C-peptide

11. (Previously Presented) The method according to claim 3, wherein said C-peptide is a fragment EGSLQ (SEQ ID NO: 2).

12. (Amended) The method according to claim 3, wherein ~~the~~ **said** patient is a human.

13. (Amended) The method according to claim 3, wherein ~~the~~ **said** ~~medicament~~ **pharmaceutical composition** contains 100 to 1800 nmol of C-peptide.

14. (Amended) The method according to claim 3, wherein ~~the~~ **said** ~~medicament~~ **C-peptide** is **in** an ~~uncompromised~~ aqueous solution.

15. (Previously Presented) The method according to claim 3, wherein said complications are diabetic nephropathy, retinopathy or neuropathy.

4. The new grounds of rejection were not necessitated by the present amendment because (i) with respect to claims 3, 10 and 12-15 the amendments merely clarify the claimed subject matter and do not introduce any new claim elements that that are substantially different from those previously presented, and (ii) with respect to claim 11, the claim was not amended.

5. Specifically the current amendment to claim 3 clarifies only the form of the claim and does not substantially change its scope. In particular the current amendment effectively replaces the term "once daily dose" with the term "once daily administration". Applicants note that the instant specification (paragraph [0025] of US application 10/575,701), defines these terms identically, as shown below. Thus the amended claim is substantially the same scope as the previously pending claim, and the Applicant's amendment cannot have necessitated the new art rejection.

> [0025] Reference to a `once daily dose` or `once daily administration` means, of course, not only that the medicament itself is only given once per day but that the patient receives no other C-peptide treatment. Such instructions may be made clear by the prescribing physician and/or in literature accompanying the packaged medication. The medicament may be adapted for once daily administration. This does not imply the presence of substances which act as release rate controlling agents, indeed the most preferred formulation of the invention is an uncompromised aqueous solution. However, the fact that a single, rather than multiple, dose is given may be reflected in the amount of active agent administered in the single dose, which may be more than would typically be administered in a dose prepared for thrice daily administration for example. Thus, different amounts may be given in a single dose, which may be greater than the amounts which would be administered in a dose intended for administration more than once. Thus, a single dose may have a higher concentration of active agent or the dose may be administered in a greater amount, e.g. a greater volume. Specific doses are described below. A once daily dose does not cover a continuous administration and is distinct therefrom. A once daily dose hence is directed to only one administration per day of the C-peptide treatment whereas a continuous administration would be constantly administering C-peptide treatment, or administering it over a prolonged period of time. [US App. 10/575,701, page 2].

6. Applicants also respectively point out that Claim 11 was not amended in the response to the Office Action, and yet received a new ground for rejection in the last Office Action.

7. Reconsideration and withdrawal of the finality of the rejections presented in the last Office Action is respectfully requested based on fact that the amendments introduced into the claims did not necessitate the new art rejection because they did not substantially change the scope of the claims in question, nor were based on information submitted in an information disclosure statement filed by applicants.

8. MPEP 706.07(a) states in relevant part:

> "Under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicants amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)...."
>
> "Furthermore, a second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art."

9. **Conclusions:**

According to the MPEP 706.07(a) a final rejection is not proper if it introduces a new ground of rejection which was not necessitated by the applicants' amendments or if it is based on new information that was not submitted in an information disclosure statement by the Applicant. In the current situation, the current amendments to the claims corrected only matters of form, and did not substantially change the claim scope, and the new art rejection was based on a new reference cited by the examiner and not the applicant. Accordingly it is concluded that the final rejection was premature and should be reconsidered and withdrawn.

No Fee is believed due in connection with the filing of this petition. However, the Commissioner is authorized to charge any additional fees that may be required in connection with this submission, including petition fees and extension of time fees, or to credit any overpayments to Deposit Account No. 50-4297

Respectfully submitted,

February 11, 2010

Date

/Dennis A. Bennett/

Dennis A. Bennett, Reg. No. 34,547

Attorney for Applicants

Global Patent Group, LLC

10411 Clayton Road

Suite 304

St. Louis, MO 63131

TELE: (314) 567-7788

FAX: (314) 567-9595